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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,086	12/05/2003	Fred H. Burbank	R0367-02501	8823

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EXAMINER	
DRYDEN, MATTHEW DUTTON	
ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/729,086	BURBANK ET AL.	
	Examiner	Art Unit	
	Matthew D. Dryden	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-54 and 66-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-48,51-54,66-69 and 72-76* is/are rejected.

7)☒ Claim(s) *49,50,71,72* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/5/03, 5/27/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. [1] as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosures of the prior-filed applications, Application Nos. 09/146,185, 09/159,467, 09/556187, 09/477,255, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The claims of the current apparatus include a radiation detector in the disclosure of the device, and the above-mentioned applications do not reference a radiation detection probe on the devices disclosed. However, Application No. 09/727,112, does meet the requirements of the claims so the priority date given to the claims in the current application is November 29, 2000.

Information Disclosure Statement

The information disclosure statement filed on 12/05/2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

Claim 29 is objected to because of the following informalities: the claim mentions the device having an "inner lumen", but there is no prior mention of the inner lumen leading up to claim 29.

Claim 34 is objected to because of the following informalities: the claim mentions accessing the sentinel lymph node with "the cannula" but there is no prior mention of the cannula leading up to claim 34.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37-39, 44, 51, 66, 73 are rejected under 35 U.S.C. 102(b) as being anticipated by Ritchart et al (5810806).

Regarding claim 37:

a. the elongated shaft having a distal end and a proximal end can be seen in Figure 1 as element 12.

a tissue cutting member at the distal end of the shaft can be seen in Figure 23 as element 20e.

at least one anchoring element extending from a position at or near the distal end of the shaft can be seen in Figure 23 element 18e.

b. a radiation detector at least a portion of which is disposed at or near the distal end of the shaft Figure 29 element 80, also refer to column 11 lines 36-56 of the specification.

Regarding claim 38, the term radial is defined in the specification as a "direction that is angled and may be generally orthogonal to a longitudinal axis", the element claimed as the anchor (element 18e) above meets these requirements and can be seen in Figure 23.

Regarding claim 39, 51, and 73 the anchoring element is curved (Figure 23, element 18e).

Regarding claims 44 and 66:

a. see the rejection applied to claim 37 above,

a deployment actuator disposed proximal of the distal end of the elongate shaft and configured to deploy the anchoring element can be seen in Figure 1, element 30.

b. see the rejection applied to claim 37 above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 25-34, 40- 43, 52-54, 74-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ritchart et al in view of Mulier et al (5431649). Regarding claims 40-43, 52-54, 74-76, Ritchart discloses the claimed invention except for the anchoring element consisting of a helical coil that extends through at least 540 degrees. Mulier et al teaches a helical coil electrode that is anchored into heart tissue (Figure 2, element 14), which serves to stabilize the catheter during R-F ablation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device taught by Ritchart with a helical coil anchor, as taught by Mulier, to make the connection between the device and the tissue more stable.

Regarding claims 25-33, the invention taught by Ritchart et al as modified with Mulier could be used for the same methods that are set-forth in claims 25-32. All of the requirements of the device needed for the method are met, and the anchoring element is capable of being radially extended from the distal end of the device to access the lymph node. Also, Mulier teaches to provide the helical coil with R-F energy to ablate

the accessed tissue (Column 1, lines 61-67). Ritchart teaches to use a slidably disposed radiation detection probe inside a secondary lumen (16g) to locate the desired tissue for cutting (Column 11, lines 34-56). Claim 31 addresses the use of a gamma camera to determine the approximate position of the sentinel lymph node, Ritchart et al suggests using a gamma camera imaging system to locate a radioisotope in the bed of a tumor (Column 3, lines 3-5). Regarding claim 32, an ultrasound imaging system is used to image the sentinel lymph node and shaft, which is suggested in Ritchart et al (Column 3, lines 39-46). Regarding claim 33, the device disclosed by Ritchart et al is capable of being used to cut and surgically remove at least one sentinel lymph node. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the device with the methods set forth in claims 25-33. Regarding claim 34, it would have been obvious to one having ordinary skill in the art at the time the invention was made to mark provide a visible mark on the skin of the patient, to help assist the user of the device to locate the insertion point of the device.

Claims 35, 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ritchart et al in view of Mulier et al as applied to claim 26 above, and further in view of Clayman (5628746). Ritchart et al, as modified discloses the claimed invention and methods except for the tissue-cutting member being an RF powered electrode. Clayman et al teaches that it is advantageous to use an electrosurgical device that utilizes radio frequency for cutting tissue because the use of radio frequency helps reduce the damage and desiccation of surrounding tissue (Column 3, lines 28-38). It would have been obvious to one having ordinary skill in the art at the time the invention

was made to further modify the device taught by Ritchart et al with a RF powered cutting instrument, taught by Clayman, to prevent the desiccation of surrounding tissue.

Claims 45 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ritchart et al in view of Mulier et al, and further in view of Goble et al (5944715). Ritchart et al discloses the claimed invention except for the anchoring device having a first and second electrical leads, one coupled to a radially extending wire and the other to the patient. Goble et al teaches an electrode assembly that comprises a tissue treatment electrode and a return electrode, that is beneficial because it requires very small electrodes and the inter electrode spacing becomes very small, limiting the interference (Column 2, lines 1-14). It would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the device taught by Ritchart et al with an anchoring device comprising two electrodes, as taught by Goble et al, to decrease the interference across the electrode and increase the efficiency of the emitted RF energy.

Claims 46-48, and 67-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ritchart et al in view of Clayman. Ritchart discloses the claimed invention except for the arcuate wire tissue-cutting member (element 20e, Figure 23) being an RF electrode. Clayman et al teaches that it is advantageous to use an electrosurgical device that utilizes radio frequency for cutting tissue because the use of radio frequency helps reduce the damage and desiccation of surrounding tissue (Column 3, lines 28-38). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device taught by Ritchart et al with

a RF powered cutting instrument, taught by Clayman, to prevent the desiccation of surrounding tissue.

Allowable Subject Matter

Claims 49, 50, 71, and 72 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pat. No. 5,456,689 Kresch et al. discloses a method and device for tissue resection

U.S. Pat. No. 5,766,169 Fritzsch et al. discloses a medical multifunctional instrument for performing endoscopic operations

U.S. Pat. No. 5,330,470 Hagan discloses an electrosurgical treatment instrument.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew D. Dryden whose telephone number is (571) 272-6266. The examiner can normally be reached on Monday-Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MDD

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